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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,118	03/15/2004	Jui H. Wang	DNPP-02007US0	9185

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,118	WANG, JUI	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ ~~Information Disclosure Statement(s) (PTO/SB/08)~~ ~~Paper No(s)/Mail Date~~ _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Oath/Declaration

2. The objection to the oath or declaration is withdrawn in response to Applicant's arguments.

Claim Rejections - 35 USC § 102

3. Claims 1-4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US 2004/0142896 A1; effective date December 5,2002), for the reasons of record.

4. Applicant's arguments filed 2-07-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that there are only three inventors on the '896 publication, and that the same three inventors are also named in the instant application. However, contrary to Applicant's assertions, the instant application has at least one inventor different from the inventive body of the '896 publication. MPEP § 706.02(a) [R-3].II., states: "[I]n order to apply a reference under 35 U.S.C. 102(e), the inventive entity of the application must be different than that of the reference. Note that, where there are joint inventors, *only one inventor* *>needs to< *be different for the inventive entities to be different* and a rejection under 35 U.S.C. 102(e) is applicable even if there are some inventors in common between the application and the reference."

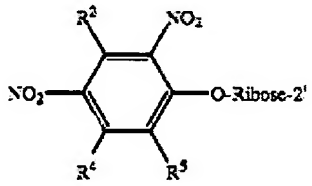
Therefore, contrary to Applicant's assertions, the claims remain rejected for the reasons of record.

Claim Rejections - 35 USC § 103

5. The rejection of claims 1-22 under 35 U.S.C. 103(a) and Double Patenting as being obvious over Wang ('438; US Patent No. 6,291,438), and Wang ('988;US Patent No. 5,858,988) in view of Hammond et al. and Parrish et al., is withdrawn. Applicant's arguments with respect to this rejection have been considered but are moot in view of the new ground(s) of rejection.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being obvious over Wang ('438; US Patent No. 6,291,438), and Wang ('988;US Patent No. 5,858,988) in view of Slattum et al. and Parrish et al.

Both Wang ('438) and ('988) describe the use of 2,4-dinitrophenyl groups to modify the 2'-O position of oligoribonucleotides (i.e. short RNA sequences), of between 10 and 40 nucleotides in length (see col. 3, lines 51-67 of '988; and col. 4, lines 6-24):



In another preferred embodiment, R^2, R^4, and R^5 are H. In a preferred embodiment, the oligoribonucleotide has a length of between 10 and 50 nucleotides or alternatively, 10 and 40 nucleotides. In another preferred embodiment, the oligoribonucleotide has a length of between 12 and 30 nucleotides. In another preferred embodiment, the oligoribonucleotide has a length of between 15 and 25 nucleotides.

Moreover, both Wang '438 and '988 (see Summary of the invention in both US Patents) describe the use of 2,4-dinitrophenyl groups for the modification of antisense oligoribonucleotides for the purpose of inhibiting the gene expression, and for use in an antisense therapeutic method.

However, Wang '438 and '988 does not teach the modification of short interfering RNA (siRNA), to produce poly-DNP-siRNA, or the use of poly-DNP-siRNA in a method for silencing the expression of a target gene comprising introducing the modified siRNA into a cell.

Slattum et al. teach compounds and methods for covalently attaching a label to an siRNA. In one embodiment, Slattum et al. teach the attachment of a DNP group to siRNA [0005], in another embodiment, Slattum et al. teach the addition of a difluoro-dinitrobenzene functional group.

[0005] There are a wide variety of reporter molecules that may be employed for covalent attachment to a labeling reagent that are useful in detection systems. All that is required is that the reporter molecule can be covalently attached to the labeling reagent and provide a signal that can be detected by appropriate means. Reporter molecules may be radioactive or non-radioactive. Non radioactive reporter molecules include fluorescent compounds, proteins, and affinity molecules (e.g. digoxin, biotin, DNP)

[0075] functional group—a group that adds functionality. This group comprises: reactive groups, charged groups, alkyl groups, polyethyleneglycol, ligands, and peptides. A reactive group is capable of undergoing further chemical reactions. Reactive groups include, but are not limited to: alkylating groups (including mustards and three-membered rings), amines, alcohols, thiols, isothiocyanates, isocyanates, acyl azides, N-hydroxysuccinimides, sufonyl chlorides, aldehydes, epoxides, carbonates, imidoesters, carboxylates, alkylposphates, arylhalides (such as difluoro-dinitrobenzene), iodoacetamides, maleimides, aziridines, acryloyl chlorides, flourobenzes, disulfides, succinamides, carboxylic acids, and activated carboxylic groups.

7. Parrish et al. provides clear guidance for the skilled artisan to introduce modifications into dsRNA, with the expectation of producing a modified dsRNA structure having increased nuclease resistance while maintaining RNA interference activity. For example, Figure 5(A-B) provides a summary of the effects of various modifications to dsRNA. Substitution of A, C, and G nucleotides with alpha-thio modifications produced dsRNA having the same level of interference activity as un-modified RNA. Moreover, Parrish et al. teach that introduction of 2'-fluoro modifications into dsRNA, had no affect on its ability to mediate RNAi in C. elegans injected with the dsRNA (see Parrish et al., Figure 5).

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Wang (both references) to comprise modification of short interfering RNA (siRNA) with 2,4-dinitrophenyl groups. One of ordinary skill in the art would have been motivated to make this modification since Slattum et al. clearly suggests the modification of siRNA with a dinitrophenyl group, and Wang et al. clearly suggests the modification of oligoribonucleotides with 2,4-dinitrophenyl groups, and Parrish et al. teach the modification of siRNA for the purpose of increasing nuclease resistance without losing interfering activity. One of ordinary skill in the art would have been motivated to make 2,4-DNP modifications of siRNA because the Wang reference clearly teaches that their modifications are suitable for short RNA molecules (i.e. oligoribonucleotides of 10 to 40 nucleotides in length), and Parrish et al. teach that modification of siRNA is feasible and well tolerated in regards to activity.

Double Patenting

8. Claim 1 remains provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/284,693.

9. Applicant's arguments filed 2-07-07 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that since the instant rejection is the only remaining grounds of rejection remaining, and the instant application is the parent application with respect to application 11/284,693. Contrary to Applicant's assertions, the instant rejection is not the only remaining rejection, therefore the instant rejection will remain as per MPEP § 804, II(B)(1).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE